



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,646	01/13/2005	Berta Kotar Jordan	4061-25PUS	9299
27799	7590	06/17/2009		
COHEN, PONTANI, LIEBERMAN & PAVANE LLP			EXAMINER	
551 FIFTH AVENUE			COLEMAN, BRENDA LIBBY	
SUITE 1210				
NEW YORK, NY 10176			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			06/17/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/521,646

**Applicant(s)**

KOTAR JORDAN ET AL.

**Examiner**

Brenda L. Coleman

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-28 is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Claims 1-28 are pending in the application.

This action is in response to applicants' amendment dated April 6, 2009. Claims 1 has been amended.

### ***Response to Arguments***

Applicants' arguments filed April 6, 2009 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1-5, 10, 11 and 25, labeled paragraph 1) maintained in the last office action. The applicants' arguments have been fully considered, however they were not found persuasive. The Applicants' stated that Form I discussed in Bunnell is actually form II defined in the present application. The applicants' stated that the present application adopts the definition of Form I and Form II provided by EP-B-733635. However, there is no indication of this in the applicants' disclosure. In the absence of the specific x-ray diffraction pattern to describe the invention, i.e. Form I, the applicants' claims are rejected under 35 U.S.C. § 102(b) as set forth herein and in the reasons of record. The applicants' further stated that to place the claims in better format, claim 1 has been

amended to further recite that the solvent mixture comprises an effective amount of form I of olanzapine as seeding crystals. However, Bunnell also states that "the artisan recognizes that crystallization processes may include seeding" in column 14, lines 25-27. It is acknowledged herein that Bunnell fails to set forth the x-ray diffraction pattern for the 2-propanol solvate, however, there is no indication what the x-ray diffraction pattern of Form I is and the rejection of Claims 1-5 is herein maintained as long as there is no clarification on the record as to what the applicants compound is, i.e. "Form I". In view of the applicants' arguments and to further clarify the record the following new grounds of rejection applies and is being added at this time in response to the applicants' filing of the request for continued examination under 37 CFR 1.114 on April 6, 2009.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bunnell et al., U.S. Patent No. 5,703,232, for reasons of record and stated above.

***Allowable Subject Matter***

2. Claims 6-28 are allowed. None of the prior art of record or a search in the pertinent art area teaches the solvates, Form A of olanzapine and process of preparing anhydrous forms and Form A of olanzapine as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624